DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEI: 3000264942

Food and Drug Administration
Baltimore District Office
6000 Metro Drive, Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5412

VL 07-200005

Certified Mail
Return Receipt Requested

WARNING LETTER

January 30, 2007

Mr. Thomas Spencer
President
Congressional Seafood Co.
7901 Oceano Avenue, Units 20, 22, 24
Jessup, MD 20794

Dear Mr. Spencer:

We inspected your seafood processing and importer establishment, located at 7901 Oceano Avenue, Units 20, 22, 24 Jessup, MD 20794 from September 25, 2006 to October 3, 2006. We found that you have serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123), and the Current Good Manufacturing Practice regulation for foods, Title 21, Code of Federal Regulations, Part 110 (21 CFR 123 & 110). In accordance with 21 CFR 123.6(g), failure of a processor of fish or fishery products to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fish or fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). The specific requirements for imported fish and fishery products are set out in 21 CFR 123.12. As an importer of fish or fishery products, you must operate in accordance with the requirements of Part 123. In accordance with 21 CFR 123.12(d), there must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with 21 CFR 123. If assurances do not exist that the imported fish or fishery products have been processed under conditions equivalent to those required of domestic processors under 21 CFR Part 123, the fish or fishery products will appear to be adulterated under Section 402(a)(4) of the Act, 21 U.S.C. §342(a)(4). Accordingly, your vacuum packaged smoked fish & surimi and imported salmon and halibut are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation and the Fish and Fisheries Products Hazards & Controls Guidance through links in FDA's home page at www.fda.gov.

Your significant violations were as follows:

- You must have a HACCP plan that at a minimum lists monitoring procedures and their frequency for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for vacuum packaged smoked fishery products and surimi lists a monitoring procedure at the chilled storage critical control point that is not adequate to control pathogens. Specifically, your plan lists the use of "digital temperature monitoring" with a visual check 3 times per day. However, this method does not ensure that proper temperatures will be continuously maintained between temperature checks and during those times when your firm is not open for business, such as holidays and weekends. FDA recommends that cooler storage temperatures be monitored with equipment that is capable of continuously monitoring temperatures and that the equipment is capable of providing a record of the temperatures or is equipped with an alarm system that provides a 24 hour alert. We further recommend a daily review of the continuous recordings and/or of the equipment itself.

- You must retain records required under 21 CFR Part 123 at the processing facility for at least 1 year after the date they were prepared in the case of refrigerated products, to comply with 21 CFR 123.9(b)(1). However, the cooler temperature logs prior to August 14, 2006 were not retained by your firm and the weekly thermometer calibration logs prior to January 2, 2006 were also not retained.

- You must implement an affirmative step which ensures that fish and fishery product(s) you import have been processed in accordance with the seafood HACCP regulation, to comply with 21 CFR Part 123.12(a)(1)(ii). However, your firm did not perform an affirmative step for the halibut and salmon manufactured by [redacted] both located in [redacted]

We may take further action if you do not promptly correct these violations. For instance, we may take further action to refuse admission of your imported fish or fishery products under Section 801(a) of the Act (21 U.S.C. §381(a)), including placing them on "detention without physical examination," seize your product(s) and/or enjoin your firm from further violating the Act.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You should include in your response documentation, such as HACCP and importer verification records, records that document the performance and results of your firm's affirmative steps, HACCP and verification records associated with your activities as a domestic processor, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

This letter may not list all the violations at your facility. You are responsible for ensuring that your seafood importer establishment operates in compliance with the Act and the seafood HACCP regulation (21 CFR Part 123). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations for the fish or fishery products that you import into the United States.

Please send your reply to the Food and Drug Administration, Attention: Kirk D. Sooter, Compliance Branch Director at the address above. If you have questions regarding any issues in this letter, please contact Mr. Sooter at 410-779-5412.

Sincerely,

Evelyn Bonnin
District Director